

Atty. Dkt. No. 034827-0703

**THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: PASUPULETI et al.

Title: OLIGONUCLEOTIDES AND  
METHODS FOR DETECTING  
HEPATITIS B VIRAL NUCLEIC  
ACIDS

Appl. No.: 10/690,282

Filing Date: 10/20/2003

Examiner: Hill, Myron G.

Art Unit: 1645

<p><b>CERTIFICATE OF MAILING</b></p> <p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450, on the date below.</p> <p><u>DIANE GARCIA</u> (Printed Name)</p> <p><u>Diane Garcia</u> (Signature)</p> <p><u>1-6-04</u> (Date of Deposit)</p>
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**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Commissioner for Patents  
PO Box 1450  
Alexandria, Virginia 22313-1450

Sir:

Applicants submit herewith on Form PTO-1449 a listing of the documents cited by or submitted to the U.S. PTO in parent application Serial No. 10/007,073, filed 12/04/2001, now United States Patent No. 6635428, granted October 21, 2003. As provided in 37 CFR §1.98(d), copies of the documents are not being provided since they were previously submitted to the United States Patent & Trademark Office in the above-identified parent application.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

**TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(b), within three (3) months of the filing date of the application.

**RELEVANCE OF EACH DOCUMENT**

All of the documents are in English.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO-1449 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872.

Respectfully submitted,

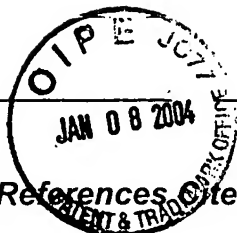
Date 1/6/04

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Registration No. 39,431

0701



# Notice of References Cited

Application/Control No.

10/007,073

Applicant(s)/Patent Under  
Reexamination  
PASUPULETI ET AL.

Examiner

Myron G. Hill

Art Unit

1648

Page 1 of 1

## U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-			
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

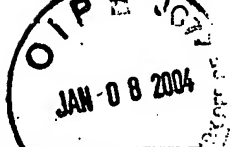
## FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

## NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
*	V	Drosten et al 2000 Vol 40 718- 724
	W	
	X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.


  
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Form PTO-1449 (MODIFIED)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 034827-0701	SERIAL NO. 10/007,073
<b>INFORMATION DISCLOSURE CITATION</b>  (Use several sheets if necessary)		APPLICANT Pasupuleti et al.	
		FILING DATE December 4, 2001	GROUP ART UNIT 1645

**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	AA	4,562,159	12/1985	Shafritz	436	501	03/31/81
	AB	4,683,195	07/1987	Mullis et al.	435	6	02/07/86
	AC	4,683,202	07/1987	Mullis	435	91	10/25/85
	AD	5,538,848	07/1996	Livak et al.	435	5	11/16/94
	AE	5,723,591	03/1998	Livak et al.	536	22.1	11/15/95
	AF	5,736,333	04/1998	Livak et al.	435	6	06/04/96
	AG	5,866,336	02/1999	Nazarenko et al.	435	6	01/03/97

**FOREIGN PATENT DOCUMENTS**

	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION	
							YES	NO
	AH	WO 89/04375	18.05.89	PCT	C12Q	1/68	X	
	AI	WO 90/13667	15.11.90	PCT	C12Q	1/68	X	
	AJ	WO 91/10746	25.07.91	PCT	C12Q	1/68	X	

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	AK	Brunetto et al., "Does HbeAg Minus HBV Modify the Course of HDV Superinfection?" The Hepatitis Delta Virus, pp. 211-216, 1991.
	AL	Brunetto et al., "Wild-type and e Antigen-Minus Hepatitis B Viruses and Course of Chronic Hepatitis," Proc. Natl. Acad. Sci. USA, 88:4186-4190, 1991.
	AM	Chen et al., "Real Time PCR for Detection and Quantitation of Hepatitis B Virus DNA," Journal of Medical Virology, 65:250-256, 2001.
	AN	Chu et al., "Postsynthesis Functionalization of Oligonucleotides," Methods in Molecular Biology, 26:145-165, 1994.

EXAMINER	DATE CONSIDERED
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\* EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include any copy of this form with next communication to applicant.



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EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE	
	BA	5,876,930	03/1999	Livak et al.	435	6	11/15/95	
	BB	5,952,202	09/1999	Aoyagi et al.	435	91.2	03/26/98	
	BC	6,030,787	02/2000	Livak et al.	435	6	12/07/98	
	BD	6,258,569 B1	07/2001	Livak et al.	435	91.1	11/08/99	
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	BE						YES	NO
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	BF	Drosten et al., "Evaluation of a New PCR Assay with Competitive Internal Control Sequence for Blood Donor Screening," Transfusion, 40:718-724, 2000.						
	BG	Fiordalisi et al., "High Genomic Variability in the Pre-C Region of Hepatitis B Virus in Anti-HBe, HBV DNA Positive Chronic Hepatitis," Journal of Medical Virology, 31:297-300, 1990.						
	BH	Hafner et al., "Isothermal Amplification and Multimerization of DNA by <i>Bst</i> DNA Polymerase," BioTechniques, 30:852-867, 2001.						
	BI	Hileman et al., "Synthesis and Characterization of Conjugates Formed Between Periodate-Oxidized Ribonucleotides and Amine-Containing Fluorophores," Bioconjugate Chem., 5:436-444, 1994.						
	BJ	Honkoop et al., "Lamivudine Resistance in Immunocompetent Chronic Hepatitis B: Incidence and Patterns," Journal of Hepatology, 26:1393-1395, 1997.						
	BK	Kaneke et al., "Detection of Serum Hepatitis B Virus DNA in Patients with Chronic Hepatitis Using the Polymerase Chain Reaction Assay," Proc. Natl. Acad. Sci. USA, 86:312-316, 1999.						
	BL	Liang et al., "Characterization and Biological Properties of a Hepatitis B Virus Isolated From a Patient Without Hepatitis B Virus Serologic Markers," Hepatology, 12(2):204-212, 1990.						
	BM	Keller et al., "Detection of Hepatitis B Virus DNA in Serum by Polymerase Chain Reaction Amplification and Microtiter Sandwich Hybridization," Journal of Clinical Microbiology, 28(6):1411-1416, 1990.						
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	CA						
FOREIGN PATENT DOCUMENTS							
	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
	CB						
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	CC	Loeb et al., "High-Throughput Quantitative Analysis of Hepatitis B Virus DNA in Serum Using the TaqMan Fluorogenic Detection System," Hepatology, 32(3):626-629, 2000.					
	CD	Meng et al., "Automated Multiplex Assay System for Simultaneous Detection of Hepatitis B Virus DNA, Hepatitis C Virus RNA, and Human Immunodeficiency Virus Type 1 RNA," Journal of Clinical Microbiology, 39(8):2937-2945, 2001.					
	CE	Mercier et al., "Simultaneous Screening for HBV DNA and HCV RNA Genomes in Blood Donations Using a Novel TaqMan PCR Assay," Journal of Virological Methods, 77:1-9, 1999.					
	CF	Pas et al., "Development of a Quantitative Real-Time Detection Assay for Hepatitis B Virus DNA and Comparison with Two Commercial Assays," Journal of Clinical Microbiology, 38(8):2897-2901, 2000.					
	CG	Pasquinelli et al., "Hepatitis B Virus Infection of Peripheral Blood Mononuclear Cells is Common in Acute and Chronic Hepatitis," Journal of Medical Virology, 31:135-140, 1990.					
	CH	Christian Oste, "Polymerase Chain Reaction," BioTechniques, 6:162-167, 1988.					
	CI	Randall K. Saiki, "Amplification of Genomic DNA," PCR Protocols: A Guide to Methods and Applications, Academic Press, Chp. 2, pp. 13-20, 1990.					
	CJ	Saito et al., "Quantitative DNA Analysis of Low-Level Hepatitis B Viremia in Two Patients with Serologically Negative Chronic Hepatitis B," Journal of Medical Virology, 58:325-331, 1999.					
	CK	Seelig et al., "Nachweis von Hepatitis-B-Virus-DNA mit der Polymerase-Kettenreaktion," DeutschMed Wochenschr, 115:1307-1312, 1990.					
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	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
	DB						
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	DC	Sumazaki et al., "Detection of Hepatitis B Virus in Serum Using Amplification of Viral DNA by Means of the Polymerase Chain Reaction," Journal of Medical Virology, 27:304-308, 1989.					
	DD	Theilmann et al., "Detection of HBV DNA in HBsAg-Positive Sera After Amplification Using the Polymerase Chain Reaction," Liver, 9:322-328, 1989.					
	DE	van Schie et al., "Semiautomated Clone Verification by Real-Time PCR Using Molecular Beacons," BioTechniques, 29:1296-1308, 2000.					
	DF	Weinberger et al., "Sensitive and Accurate Quantitation of Hepatitis B Virus DNA Using a Kinetic Fluorescence Detection System (TaqMan PCR)," Journal of Virological Methods, 85:75-82, 2000.					
	DG	Wharam et al., "Specific Detection of DNA and RNA Targets Using a Novel Isothermal Nucleic Acid Amplification Assay Based on the Formation of a Three-Way Junction Structure," Nucleic Acids Research, 29(11):1-8, 2001.					
	DH	Zaaijer et al., "Comparison of Methods for Detection of Hepatitis B Virus DNA," Journal of Clinical Microbiology, 32(9):2088-2091, 1994.					
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